#### **REMARKS**

Applicants wish to express appreciation to the Examiner for arranging her schedule to meet with applicants' representative on August 10, 2006 to discuss the instant application.

Claims 135-170 were pending. Applicants have hereinabove cancelled without prejudice claims 135-170 and have added new claims 171-200, including new independent claims 171 and 186. Dependent claims 172-185 and 187-200 correspond to a significant extent to previously pending dependent claims 136-152 and 154-170 (although some of those dependent claims were deleted without prejudice and, therefore, do not have corresponding claims in the new claim set).

No new matter has been added by this amendment. Support for new claims 171-200 may be found throughout the specification, including, more specifically, in many of the representative Examples. Upon entry of this Amendment, new claims 171-200 will be pending.

## Rejection Under 35 U.S.C. § 103(a)

In the March 1, 2006 Office Action, the Examiner rejected previously pending claims 135-170 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Latorre's U.S. Patent No. 6,517,863 (hereinafter "the '863 Patent").

In response, applicants respectfully traverse the Examiner's rejection under § 35 U.S.C. 103(a). Without conceding the correctness of the Examiner's bases for rejecting the previously pending claims and to expedite prosecution of the instant application, applicants have hereinabove cancelled without prejudice claims 135-170. Applicants submit that the presently pending claims are not obvious over the '863 Patent.

Applicants note that claims 171 and 186 are the only presently pending independent claims. Claim 171 recites:

A cosmetic composition comprising bioactive glass and a substantially anhydrous cosmetic formulation, wherein said bioactive glass comprises from about 30% to about 96% silicon dioxide (SiO<sub>2</sub>), from about 4% to about 46% calcium oxide (CaO), from about 1% to about 15% phosphorus oxide (P<sub>2</sub>O<sub>5</sub>) and up to about 35% sodium oxide (Na<sub>2</sub>O), all by weight of said bioactive glass, with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc, wherein said bioactive glass comprises from about 0.05% to about 30% by weight of said cosmetic composition, wherein said cosmetic formulation is selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products, and wherein said composition does not result in a significant skin sensitivity response when applied.

#### Claim 186 recites:

A method of making a cosmetic composition comprising combining bioactive glass with a substantially anhydrous cosmetic formulation, wherein said bioactive glass comprises from about 30% to about 96% silicon dioxide (SiO<sub>2</sub>), from about 4% to about 46% calcium oxide (CaO), from about 1% to about 15% phosphorus oxide (P<sub>2</sub>O<sub>5</sub>) and up to about 35% sodium oxide (Na<sub>2</sub>O), all by weight of said bioactive glass, with the proviso that said bioactive glass does not comprise ions of silver, copper or zinc, wherein said bioactive glass comprises from about 0.05% to about 30% by weight of said cosmetic composition, wherein said cosmetic formulation is selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products, and wherein said composition does not result in a significant skin sensitivity response when applied.

In sharp contrast to the currently pending claims, the '863 Patent (1) is directed to nails, a hard surface which is not like skin or hair; (2) describes a formulation that does not need to be gentle to the skin since it is applied to nails rather than skin or hair; (3) describes a formulation that should be applied immediately and therefore cannot provide long-lasting anti-microbial effects for the cosmetic composition itself both prior to and after application (See Col. 5, lines 50-55); and (4) describes a topical formulation that requires sufficient water to be effective and thus is not substantially anhydrous (See Col. 4, line 64 to Col. 5, line 3). For the sake of completeness each of these distinctions is described in more detail below.

## The '863 Patent Is Directed To Compositions For Nails, Not Skin Or Hair

The presently pending claims are directed, *inter alia*, to cosmetic formulations selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products. Given the types of cosmetic formulations recited in this Markush group, it is evident that such compositions are for use on skin and hair.

In sharp contrast, it is quite clear that the '863 Patent is specifically directed to compositions for use on nail surfaces. For example, referring to the compositions described in the '863 Patent, the specification states that "[such] compositions form a protective layer of hydroxyapatite or other calcium phosphate mineral on the nail body, which effectively hardens and increases the durability of the nail." (See last paragraph of Summary of Invention at Col. 3, lines 1-6.)

Applicants respectfully submit that given the drastically different nature of hair and skin as compared to nails, this distinction alone is dispositive.

The '863 Patent Describes Compositions That Do Not Have To Be Gentle To Skin And Hair

Since the '863 Patent describes compositions for use on nail surfaces, such compositions do not have to be gentle. In contrast, the presently claimed invention provides compositions which are gentle to skin and hair and do not result in a significant skin sensitivity response when applied. Example 15 of applicants' specification confirms that representative examples of the presently claimed compositions do not irritate the skin or result in any perceivable allergic hypersensitivity. This is particularly advantageous in compositions intended for use in hair and skin formulations given the particulate nature of bioactive glass.

# The '863 Patent Does Not Describe Long-Lasting Compositions

The '863 Patent does not describe <u>stable</u> cosmetic compositions (or methods of making such compositions) comprising bioactive glass and a substantially anhydrous cosmetic formulation selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products. Rather, the '863 Patent discloses that:

It is preferable that the glass not be significantly prereacted prior to application to the nails. This can be achieved, for example, by mixing the bioactive glass and water to form the compositions and applying the composition to the nails immediately after mixing. [Emphasis supplied.] [Col. 5, lines 52-56.]

In contrast, the presently claimed invention provides, *inter alia*, stable, long-lasting compositions (and methods of making same) comprising bioactive glass and a substantially anhydrous cosmetic formulation selected from the group consisting of lip products, face powder products, hair care products, deodorant products and soap products. Such compositions have an extended duration of effect both prior to and after application to hair or skin, and, unlike the nail hardening compositions in the '863 Patent, the presently claimed compositions do not need to be used immediately upon combination.

The '863 Patent also concedes the need for additional anti-microbial additives to provide a significant anti-microbial effect even in the context of nail hardening and strengthening compositions intended for immediate use. In contrast, the presently claimed invention provides significant and long-lasting anti-microbial effects without the use of anti-microbial additives both prior to and after application to hair or skin.

# The '863 Patent Does Not Describe Substantially Anhydrous Compositions

As specifically recited in independent claims 171 and 186, the presently pending claims require the presence of a substantially anhydrous cosmetic formulation selected from the group

consisting of lip products, face powder products, hair care products, deodorant products and soap products. Since the '863 Patent does not disclose, teach or suggest a cosmetic composition comprising a substantially anhydrous cosmetic formulation, much less the particularly recited cosmetic formulations, the '863 Patent cannot render obvious the presently pending claims.

More particularly, the '863 Patent stresses the criticality of using aqueous solutions or hydrophilic ("water-loving") polymers for the nail hardening compositions in the '863 Patent to work. For instance, the '863 Patent discloses using either an aqueous solution or, alternatively, a gel based formulation (which uses a hydrophilic polymer) to create a layer of hydroxyapatite or other calcium phosphate mineral on the nail. (Col. 2, lines 48-61.) The '863 Patent further states that "[a]n effective nail-enhancing amount of bioactive glass is defined as an amount capable of providing the nail surface with at least a thin coating of hydroxyapatite." (Col. 3, lines 30-33.) The '863 Patent also states that the theory behind the invention is the "adsorption of hydronium ions from a solution and a release of sodium and/or calcium ions..." (Emphasis supplied.) (Col. 3, lines 38-40.) Thus, aqueous solutions and hydrophilic polymer solutions are critical to the '863 Patent.

Importantly, the '863 Patent discloses beyond doubt the criticality (for the invention described in the '863 Patent) of <u>aqueous or hydrophilic-based compositions</u> when describing formulations which include bioactive glass. In doing so the '863 Patent states.

The bioactive glass or extract of bioactive glass <u>may be</u> <u>administered to the nail in a topical formulation</u>, such as in the form of a suspension, lotion, cream (water-in-oil emulsion) or gel, <u>provided that the formulation includes a sufficient amount of water</u> such that the ions can be formed and allowed to react with the nail to form the hydroxyapatite layer. [Emphasis supplied.] [Col. 4, line 62 - Col. 5, line 3.]

Example 1 in the '863 Patent (the only example in which an arguably cosmetic formulation comprising bioactive glass is described), used an equal volume of bioactive glass and <u>water</u> to form a paste. (See Col. 6, lines 45-62.) Applicants respectfully maintain that this distinction alone also is dispositive.

Given each of the four major distinctions discussed above, but especially in light of those four distinctions taken together, applicants respectfully submit that the presently pending independent claims are not rendered obvious by the '863 Patent.

## **Dependent Claims**

Applicants maintain that new dependent claims 172-185 and 187-200 are not rendered obvious by the '863 Patent in view of Vatter's U.S. Patent No. 6,224,888 ("the '888 Patent"). Applicants, therefore, traverse that rejection.

In the March 1, 2006 Office Action, the Examiner relies on the '888 Patent for the proposition that it was known in the cosmetic art to employ cosmetic additives. There should be no disagreement, however, between the Examiner and applicants' representative that, as applied to the newly presented claims, the '888 Patent fails to cure the deficiencies of the '863 Patent (i.e., those four significant distinctions, discussed above, between the presently pending claims and the '863 Patent).

### Conclusion

In view of the foregoing, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the March 1, 2006 Final Office Action and allow the presently pending claims, namely claims 171-200.

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No fee, other than the fee for a three-month extension of time, is believed to be necessary

in connection with the filing of this Amendment. If any fee is deemed to be necessary,

applicants hereby authorize such fee to be charged to Deposit Account No. 50-0540.

If a telephone interview would be of assistance in advancing prosecution of this

application, applicants' undersigned attorney encourages the Examiner to telephone him at the

number provided below.

Respectfully submitted,

Dated: August 31, 2006

/Robert E. Alderson/

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